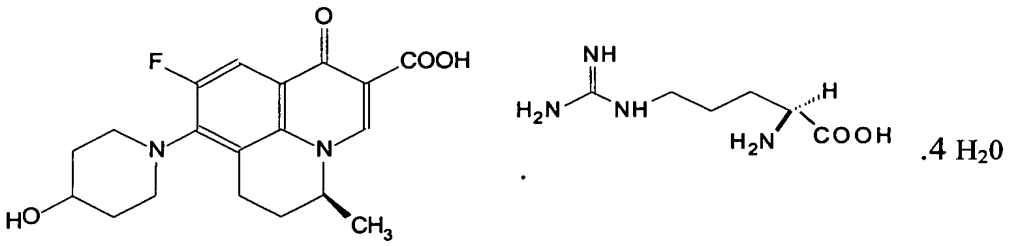
CLAIMS

1. (original) S-(-)-9-fluoro-6,7-dihydro-8-(4-hydroxypiperidin-1-yl)-5-methyl-1-oxo-1H,5H-benzo[i,j] quinolizine-2-carboxylic acid L-arginine salt tetrahydrate of the formula I



Formula I

in a crystalline form.

2. (original) A S-(-)-9-fluoro-6,7-dihydro-8-(4-hydroxypiperidin-1-yl)-5-methyl-1-oxo-1H,5H-benzo [i,j] quinolizine-2-carboxylic acid L-arginine salt tetrahydrate having the following X-ray powder diffraction data: (2θ):4.86± 0.2,14.10 ± 0.2, 14.90 ± 0.2, 19.35 ± 0.2, 22.20 ± 0.2, 23.04 ± 0.2, 23.54 ± 0.2, 28.44 ± 0.2, 39.44 ± 0.2.

3. . (original) A S-(-)-9-fluoro-6,7-dihydro-8-(4-hydroxypiperidin-1-yl)-5-methyl-1-oxo-1H,5H-benzo [i,j]quinolizine-2-carboxylic acid L-arginine salt tetrahydrate having the following X-ray powder diffraction data: (2θ):4.86± 0.2,14.10 ± 0.2, 14.90 ± 0.2, 19.35 ± 0.2, 22.20 ± 0.2, 23.04 ± 0.2, 23.54 ± 0.2, 28.44 ± 0.2, 39.44 ± 0.2.; a DSC exotherm at 194. 93°C (onset at 189.42°C) and one endotherm at 87.83°C, 144.03°C and 251.26°C and a water content of between 11.0 to 12.5% by weight as determined by titration according to Karl Fischer.

4. . (original) The S-(-)-9-fluoro-6,7-dihydro-8-(4-hydroxypiperidin-1-yl)-5-methyl-1-oxo-1H,5H-benzo [i,j]quinolizine-2-carboxylic acid L-arginine salt tetrahydrate according to claim 2, having a DSC exotherm at 194. 93°C (onset at 189.42°C) and one endotherm at 87.83°C, 144.03°C and 251.26°C.

5. . (original) The S-(-)-9-fluoro-6,7-dihydro-8-(4-hydroxypiperidin-1-yl)-5-methyl-1-oxo-1H,5H-benzo[i,j]quinolizine-2-carboxylic acid L-arginine salt tetrahydrate according to claim 2, wherein the solubility in a solution of pH 9.5 is 5.0 mg/ml.

6. . (original) The S-(-)-9-fluoro-6,7-dihydro-8-(4-hydroxypiperidin-1-yl)-5-methyl-1-oxo-1H,5H-benzo[i,j] quinolizine-2-carboxylic acid L-arginine salt tetrahydrate according to claim 3, wherein the solubility in a solution of pH 9.5 is 5.0 mg/ml.

7. . (original) The S-(-)-9- fluoro-6,7-dihydro-8-(4-hydroxypiperidin-1-yl)-5-methyl-

1-oxo-1H,5H-benzo[i,j]quinolizine-2-carboxylic acid L-arginine salt tetrahydrate according to claim 1, wherein the water content is between 11.0 % and 12.5 % by weight as determined by titration according to Karl Fischer.

8. (original) The S-(-)-9-fluoro-6,7-dihydro-8-(4-hydroxypiperidin-1-yl)-5-methyl-1-oxo-1H,5H-benzo [i,j]quinolizine-2-carboxylic acid L-arginine salt tetrahydrate according to claim 2, wherein the water content is between 11.0 % and 12.5 % by weight as determined by titration according to Karl Fischer.

9. (original) A process for the manufacture of S-(-)-9-fluoro-6,7-dihydro-8-(4-hydroxypiperidin-1-yl)-5-methyl-1-oxo-1H,5H-benzo[i,j]quinolizine-2-carboxylic acid L-arginine salt tetrahydrate comprising the steps of:

a) heating a suspension of S-(-)-9-fluoro-6,7-dihydro-8-(4-hydroxypiperidin-1-yl)-5-methyl-1-oxo-1H, 5H-benzo[i,j]quinolizine-2-carboxylic acid L-arginine salt tetrahydrate in an organic solvent and water at 70-80°C to obtain a clear solution;
b) cooling the solution to provide a crystalline substance;
c) isolating the crystalline form of S-(-)-9-fluoro-6,7-dihydro-8-(4-hydroxypiperidin-1-yl)-5-methyl-1-oxo-1H, 5H-benzo[i,j]quinolizine-2-carboxylic acid L-arginine salt tetrahydrate tetrahydrate at 30°C - 35°C by filtration or centrifugation;
d) air drying of the crystalline form of S-(-)-9-fluoro-6,7-dihydro-8-(4-hydroxypiperidin-1-yl)-5-methyl-1-oxo-1H,5H-benzo[i,j] quinolizine-2-carboxylic acid L-arginine salt tetrahydrate tetrahydrate at a temperature between 30°C - 35°C.

10. (original) A process according to claim 9, wherein the organic solvent is acetone or acetonitrile.

11. (original) The process according to claim 9 wherein the organic solvent is acetone.

12. (original) A composition comprising S-(-)-9-fluoro-6,7-dihydro-8-(4-hydroxypiperidin-1-yl)-5-methyl-1-oxo-1H,5H-benzo[i,j]quinolizine-2-carboxylic acid L-arginine salt tetrahydrate according to claim 1 and a carrier, diluent, solvent or excipient.

13. (original) A composition comprising S-(-)-9-fluoro-6,7-dihydro-8-(4-hydroxypiperidin-1-yl)-5-methyl-1-oxo-1H,5H-benzo[i,j]quinolizine-2-carboxylic acid L-arginine salt tetrahydrate according to claim 2 and a carrier, diluent, solvent or excipient.

14. (original) A composition comprising S-(-)-9-fluoro-6,7-dihydro-8-(4-

hydroxypiperidin-1-yl)-5-methyl-1-oxo-1H,5H-benzo[i,j]quinolizine-2-carboxylic acid L-arginine salt tetrahydrate tetrahydrate according to claim 3 and a carrier, diluent, solvent or excipient.

15. (previously presented) A method for treating a disease caused by a - bacterial infection in a mammal comprising administering an effective amount of S-(-)-9-fluoro-6,7-dihydro-8-(4-hydroxypiperidin-1-yl)-5-methyl-1-oxo-1H,5H-benzo[i,j]quinolizine-2-carboxylic acid L-arginine salt tetrahydrate according to claim 1 to the mammal in need thereof.

16. (previously presented) A method for treating a disease caused by a bacterial infection in a mammal comprising administering an effective amount of S-(-)-9-fluoro-6,7-dihydro-8-(4-hydroxypiperidin-1-yl)-5-methyl-1-oxo-1H,5H-benzo[i,j]quinolizine-2-carboxylic acid L-arginine salt tetrahydrate according to claim 2 to the mammal in need thereof.

17. (previously presented) A method for treating a disease caused by a bacterial infection in a mammal comprising administering an effective amount of S-(-)-9-fluoro-6,7-dihydro-8-(4-hydroxypiperidin-1-yl)-5-methyl-1-oxo-1H,5H-benzo[i,j]quinolizine-2-carboxylic acid L-arginine salt tetrahydrate according to claim 3 to the mammal in need thereof.

Claims 18 - 20 (cancel)

21. (previously presented) A method for treating a bacterial infection in a mammal comprising administering an effective amount of S-(-)-9-fluoro-6,7-dihydro-8-(4-hydroxypiperidin-1-yl)-5-methyl-1-oxo-1H,5H-benzo[i,j]quinolizine-2-carboxylic acid L-arginine salt tetrahydrate according to claim 1 to the mammal in need thereof.

22. (previously presented) A method for treating a bacterial infection in a mammal comprising administering an effective amount of S-(-)-9-fluoro-6,7-dihydro-8-(4-hydroxypiperidin-1-yl)-5-methyl-1-oxo-1H,5H-benzo[i,j]quinolizine-2-carboxylic acid L-arginine salt tetrahydrate according to claim 2 to the mammal in need thereof.

23. (previously presented) A method for treating a bacterial infection in a mammal comprising administering an effective amount of S-(-)-9-fluoro-6,7-dihydro-8-(4-hydroxypiperidin-1-yl)-5-methyl-1-oxo-1H,5H-benzo[i,j]quinolizine-2-carboxylic acid L-arginine salt tetrahydrate according to claim 3 to the mammal in need thereof.

24. (previously presented) The method according to claim 15 wherein the disease is impetigo,

pneumonia, bronchitis, pharyngitis, endocarditis, urinary tract infection, gastro-intestinal infection or bacteremia.

25. (previously presented) The method according to claim 16 wherein the disease is impetigo, pneumonia, bronchitis, pharyngitis, endocarditis, urinary tract infection, gastro-intestinal infection or bacteremia.

26. (previously presented) The method according to claim 17 wherein the disease is impetigo, pneumonia, bronchitis, pharyngitis, endocarditis, urinary tract infection, gastro-intestinal infection or bacteremia.

Claims 27-29. (cancel)

30. (previously presented) The method according to claim 15 wherein the disease is caused by bacteria selected from the group consisting of *Staphylococcus aureus*, coagulase negative *Staphylococci*, methicillin-resitant *Staphylococcus aureus*, methicillin-resistant coagulase negative *Staphylococci*, *Enterococci*, beta-haemolytic *Streptococci*, viridans group of *Streptococci*, multi-drug resistant *M. tuberculosis, M. intracellulare, M. avium, Chryseobacterium meningosepticum, Chryseobacterium indologense , E.coli, Klebsiella, Proteus, Serratia, Citrobacter, and Pseudomonas*.

31. (previously presented) The method according to claim 16 wherein the disease is caused by bacteria selected from the group consisting of *Staphylococcus aureus*, coagulase negative *Staphylococci*, methicillin-resitant *Staphylococcus aureus*, methicillin-resistant coagulase negative *Staphylococci*, *Enterococci*, beta-haemolytic *Streptococci*, viridans group of *Streptococci*, multi-drug resistant *M. tuberculosis, M. intracellulare, M. avium, Chryseobacterium meningosepticum, Chryseobacterium indologense , E.coli, Klebsiella, Proteus, Serratia, Citrobacter, and Pseudomonas*.

32. (previously presented) The method according to claim 17 wherein the disease is caused by bacteria selected from the group consisting of *Staphylococcus aureus*, coagulase negative *Staphylococci*, methicillin-resitant *Staphylococcus aureus*, methicillin-resistant coagulase negative *Staphylococci*, *Enterococci*, beta-haemolytic *Streptococci*, viridans group of *Streptococci*, multi-drug resistant *M. tuberculosis, M. intracellulare, M. avium,*

Chryseobacterium meningosepticum, Chryseobacterium indologense , E.coli, Klebsiella, Proteus, Serratia, Citrobacter, and Pseudomonas.

Claims 33-35 (cancel)

36. (previously presented) The method according to claim 21 wherein the infection is caused by bacteria selected from the group consisting of *Staphylococcus aureus*, coagulase negative *Staphylococci*, methicillin-resitant *Staphylococcus aureus*, methicillin-resistant coagulase negative *Staphylococci*, *Enterococci*, beta-haemolytic *Streptococci*, viridans group of *Streptococci*, multi-drug resistant *M. tuberculosis, M. intracellulare, M. avium, Chryseobacterium meningosepticum, Chryseobacterium indologense , E.coli, Klebsiella, Proteus, Serratia, Citrobacter, and Pseudomonas.*

37. (previously presented) The method according to claim 22 wherein the infection is caused by bacteria selected from the group consisting of *Staphylococcus aureus*, coagulase negative *Staphylococci*, methicillin-resitant *Staphylococcus aureus*, methicillin-resistant coagulase negative *Staphylococci*, *Enterococci*, beta-haemolytic *Streptococci*, viridans group of *Streptococci*, multi-drug resistant *M. tuberculosis, M. intracellulare, M. avium, Chryseobacterium meningosepticum, Chryseobacterium indologense , E.coli, Klebsiella, Proteus, Serratia, Citrobacter, and Pseudomonas.*

38. (previously presented) The method according to claim 23 wherein the infection is caused by bacteria selected from the group consisting of *Staphylococcus aureus*, coagulase negative *Staphylococci*, methicillin-resitant *Staphylococcus aureus*, methicillin-resistant coagulase negative *Staphylococci*, *Enterococci*, beta-haemolytic *Streptococci*, viridans group of *Streptococci*, multi-drug resistant *M. tuberculosis, M. intracellulare, M. avium, Chryseobacterium meningosepticum, Chryseobacterium indologense , E.coli, Klebsiella, Proteus, Serratia, Citrobacter, and Pseudomonas.*

39. (new) A solid composition comprising S-(-)-9-fluoro-6,7-dihydro-8-(4-hydroxypiperidin-1-yl)-5-methyl-1-oxo-1H,5H-benzo[i,j]quinolizine-2-carboxylic acid L-arginine salt tetrahydrate according to claim 1 and a pharmaceutically acceptable carrier or excipient.

40. (new) A method for treating a bacterial infection in a mammal comprising

administering an effective amount of a composition according to claim 39 to the mammal in need thereof.

41. (new) A method for treating a disease caused by a bacterial infection in a mammal comprising administering an effective amount of a composition according to claim 39 to the mammal in need thereof.

42. (new) The method according to claim 41 wherein the disease is impetigo, pneumonia, bronchitis, pharyngitis, endocarditis, urinary tract infection, gastro-intestinal infection or bacteremia.

43. (new) The method according to claim 41 wherein the disease is caused by bacteria selected from the group consisting of *Staphylococcus aureus*, coagulase negative *Staphylococci*, methicillin-resitant *Staphylococcus aureus*, methicillin-resistant coagulase negative *Staphylococci*, *Enterococci*, beta-haemolytic *Streptococci*, viridans group of *Streptococci*, multi-drug resistant *M. tuberculosis, M. intracellulare, M. avium, Chryseobacterium meningosepticum, Chryseobacterium indologense , E.coli, Klebsiella, Proteus, Serratia, Citrobacter, and Pseudomonas.*

44. (new) The method according to claim 40 wherein the infection is caused by bacteria selected from the group consisting of *Staphylococcus aureus*, coagulase negative *Staphylococci*, methicillin-resitant *Staphylococcus aureus*, methicillin-resistant coagulase negative *Staphylococci*, *Enterococci*, beta-haemolytic *Streptococci*, viridans group of *Streptococci*, multi-drug resistant *M. tuberculosis, M. intracellulare, M. avium, Chryseobacterium meningosepticum, Chryseobacterium indologense , E.coli, Klebsiella, Proteus, Serratia, Citrobacter, and Pseudomonas.*